



PATENT  
Customer No. 22,852  
Attorney Docket No. **6832.0013**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Craig A. ROSEN et al. ) Group Art Unit: 1653  
)  
Application No.: 09/832,929 ) Examiner: Hope A. Robinson  
)  
Filed: April 12, 2001 )  
)  
For: ALBUMIN FUSION PROTEINS )  
)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants bring to the attention of the Examiner the documents listed on the PTO 1449s attached (44 pages and 2 pages). This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

04/06/2004 SSANDARA 00000001 09832929  
01 FC:1806 180.00 DP

English translations of the following non-English patent documents are enclosed with the relevant documents:

JP 2 227079  
JP 3 201987  
WO 93/00437  
WO 93/15200  
WO 95/30759  
WO 99/15193

English translations of the following non-English articles are also enclosed with the relevant documents:

Becquart, J., "Les Syncopes ou Malaises D'Origine Vasculaire," *Soins*, 504: 4-8 (1987).

Becquart J., et al., "Pronostic du Syndrome de Wolff-Parkinson-White chez le Nourrisson," *Arch. Mal. Coeur* 81:695-700 (1988).

Becquart, J., et al., "Insuffisance Aortique Argue Rhumatoide Traitee Par un Remplacement Valvulaire," *Arch. Mal. Coeur* 84:987-989 (1991).

Becquart, J., et al., "Les Pheochromocytomes Malins," *Annales De Cardiologie Et D'Andeliologie*, 36:191-196 (1987).

Cai, M. et al., "Development and Application of Hybridoma Secreting Monoclonal Antibody Against Poly-Human Serum Albumin" *J. WCUMS* 20(2):134-136 (1989).

Chen, Y-M., "Pulmonary Nocardiosis with Cerebral Abscess Successfully Treated by Medication Alone—A Case Report," *Chin. Med. J. (Taipei)* 47:294-298 (1991).

Chen, Y-M., et al., "Neurofibromatosis with Interstitial Pulmonary Fibrosis—Case Report and Literature Review," *Chin. Med. J. (Taipei)* 42:213-218 (1988).

Chen, Z., et al., "Enhancing the Immunogenicity of the preS Antigen of Hepatitis B Virus by Genetically Fusing it with Interleukin-2," *Natl. Med. J. China* 76(1):34-37 (1996).

Dmitrenko, V.V., et al., "Heterogeneity of the Polyadenylation Site of mRNA Coding for Human Serum Albumin," *Genetika* 26(4):765-769 (1990).

Fedorchenko, S.V., et al., "Is it Possible to Overcome Resistance of Patients with Chronic Hepatitis B to Antiviral Therapy Because of Production of Antibodies to Recombinant  $\alpha_2$ -Interferon?" *Voprosy Virusologii* 5:218-220 (1994).

Hannebicque, G., et al., "Manifestations Cardiaques De La Maladie De Lyme," *Ann. Cardiol. Angelol.* 38:87-90 (1989).

Huang S-Z., et al., "A Study of Transgenic IFV Cattle with the Human Serum Albumin Gene Integrated," *ACTA Genetic Sinica* 27(7):573-579 (2000).

Hwang, G-S., et al., "Small Bowel Perforation Secondary to Metastatic Pulmonary Carcinoma," *Chin. Med. J. (Taipei)* 41(2):159-164 (1988).

Le Bras, M., et al., "Epidemiologie et Clinique des Maladies Tropicales D'importation," *La Revue de Medicine Interne* 13:205-210 (1992).

Matsuda, Y., et al., "Human Serum Albumin Variants," *Tanpakushitu Kakusan Koso* 33(5):930-935 (1988).

Ohtani, W., et al., "Structure of Tecombinant Human Serum Albumin from *Pichia pastoris*," *J. Pharm. Soc. Japan* 117(4):220-232 (1997).

Ruzgas, T.A., et al., "Ellipsometric Study of Antigen-Antibody Interaction at the Interface Solid/Solution," *Biofizika*, 37 (1): 56-61 (1992).

Takeshima, K., et al., "Ligand Binding Properties and Esterase-like Activity of Recombinant Human Serum Albumin," *Regular Articles Yakugaku Zasshi* 116(8):622-629 (1996).

Thery, C., et al., "Filter Cave Temporaire Permettant le Diagnostic et al Fibrinolyse Chez les Patients Suspects d'embolie Pulmonaire Massive," *Arch. Mal. Coeur* 84:525-530 (1991).

Vincent, M.P., et al., "Surdosage a l'halofantrine," *La Presse Medicale* 3:131 (1992).

Yeh, P-F., et al., "Haemophilus Infection in Chronic Obstructive Pulmonary Disease Patients," *Chin. Med. J. (Taipei)*, 44:57-60 (1989).

Yeh, P-F., et al., "Tuberculosis Bacteremia," *China Med. J. (Taipei)* 47(4):290-293 (1991).

Zhong, S., et al., "Experimental Research on Inhibition of Hepatitis B Virus of Targeted Hepatocytes In Vitro by Antisense Oligonucleotides," *National Medical Journal of China* 75(7):392-395 (1995).

Zhou, C.S., et al., "A Monoclonal Antibody Directed Against an Eenediyne Antitumor Antibiotic and its Preliminary Application," *ACTA Pharmaceutica Sinica* 32(1):28-32 (1997).

In lieu of English translations and as a concise statement of relevance of each, English language Derwent abstracts of the following non-English patent documents are enclosed with the following documents:

JP 1 117790  
CN 1235981 A  
CN 1239103 A  
JP 2 117384  
JP 3 27320  
JP 4 211375  
JP 5 292972  
JP 6 38771  
JP 6 22784  
JP 8 53500  
JP 8 59509  
JP 8 51982

In lieu of a translation or statement of relevance, English-language patent equivalents and patent family information have been submitted for the following non-English patent documents:

EP 0 236 210 A1 (equivalent to U.S. Pat. Nos., 5,100,784 and 5,187,261)  
EP 0 511 912 A1 (equivalent to U.S. Pat. No. 5,646,012)  
EP 0 711 835 A1 (equivalent to U.S. Pat. No. 6,114,146)  
FR 2,635,115 (equivalent to EP 0 361 991 A2)  
FR 2,719,593 (equivalent to WO 95/30759, translated as above)  
DE 37 23 781 A1 (equivalent to UK Pat. Application No. GB 2 193 631 A)  
WO 93/15199 (equivalent to U.S. Pat. No. 5,876,969)  
WO 93/15211 (equivalent to U.S. Pat. No. 5,665,863)  
WO 96/14409 (equivalent to AU Pat. No. 704,594)  
WO 96/14416 (equivalent to U.S. Pat. No. 6,149,911)

Finally, the following U.S. patent applications are already before the Examiner and have been considered. Therefore, the following applications are being cited to place them on record:

09/832,501	Ballance et al.	Filed 4/12/01
09/833,041	Rosen et al.	Filed 4/12/01
09/833,111	Rosen et al.	Filed 4/12/01
09/833,117	Rosen et al.	Filed 4/12/01
09/833,118	Rosen et al.	Filed 4/12/01

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please  
charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn  
Charles E. Van Horn  
Reg. No. 40,266

Dated: April 5, 2004

## SUPPLEMENTAL INFORMATION DISCLOSURE CITATION

Atty. Docket No. 6832.0013	Appln. No. 09/832,929
Applicant Craig A. Rosen et al.	
Filing Date April 21, 2001	Group: 1653

## the specification U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,869,445	2/9/99	Cheever et al.	514	2	

## FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
WO 90/14357	11/29/90	PCT			
WO 92/20798	11/26/92	PCT			
WO 93/16185	8/19/93	PCT			
WO 95/21862	8/17/95	PCT			
WO 96/20514	7/4/96	PCT			
WO 97/24438	7/10/97	PCT			
WO 98/17797	4/30/98	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

ERBB2: v-erb-b2 erythroblastic leukemia viral oncogene homolog 2, neuro/glioblastoma derived oncogene homolog (avian); Locus ID: 2064 (from NCBI LocusLink) (June 6, 1986)
USP Dictionary of USAN and International Drug Names; Trastuzumab. Immunoglobulin G1: CAS-180288-69-1 (2001)
Nucleotide sequence of a miniribozyme; Accession number AAA58637 (from Geneseq Version 79.0) (Oct. 20, 2000)
v-erb-b2 erythroblastic leukemia viral oncogene homolog 2; Accession number NP_004439 (from NCBI GenBank) (Dec. 23, 2003)
Hypothetical protein XP_008603; Accession number XP_008603 (from NCBI GenBank) (Oct. 16, 2001)

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
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## SUPPLEMENTAL INFORMATION DISCLOSURE CITATION

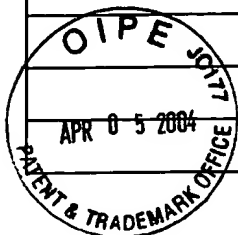
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EST name: yj20g05.s1; Accession number R82666 (from NCBI GenBank) (June 14, 1995)

EST name: yf18b08.r1; Accession number R08222 (from NCBI GenBank) (April 5, 1995)

EST name: F1\_1087D; Accession number R29573 (from NCBI GenBank) (April 25, 1995)



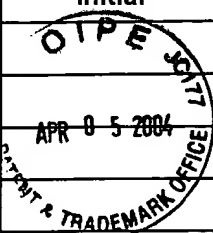
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**INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)

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**U.S. PATENT DOCUMENTS**

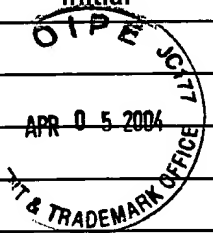
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	4,336,248	06/22/82	Bonhard et al.	424	101	
	4,751,180	06/14/88	Cousens et al.	435	68	
	4,765,980	08/23/88	DePrince et al.	424	108	
	4,801,575	01/31/89	Pardridge et al.	514	4	
	4,914,027	04/03/90	Knapp et al.	435	69.6	
	4,959,314	09/25/90	Mark et al.	435	69.1	
	4,970,300	11/13/90	Fulton et al.	530	383	
	5,045,312	09/03/91	Aston et al.	424	85.8	
	5,073,627	12/17/91	Curtis et al.	530	351	
	5,100,784	03/31/92	Latta et al.	435	69.7	
	5,116,944	05/26/92	Sivam et al.	530	362	
	5,116,964	5/26/92	Capon et al.	536	23.5	
	5,187,261	02/16/93	Latta et al.	530	363	
	5,223,408	6/29/93	Goeddel et al.	435	69.3	
	5,272,070	12/21/93	Lehrman et al.	435	172.1	
	5,302,697	04/12/94	Goodey et al.	530	325	
	5,330,971	07/19/94	Wells et al.	514	2	
	5,336,603	08/09/94	Capon et al.	435	69.7	
	5,380,712	01/10/95	Ballance et al.	514	12	
	5,612,196	03/18/97	Becquart et al.	435	69.6	
	5,641,663	6/24/97	Garvin et al.	435	172.1	

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	5,646,012	07/08/97	Fleer et al.	435	69.1	
	5,665,863	09/09/97	Yeh et al.	530	351	
	5,679,777	10/21/97	Anderson et al.	530	385	
	5,705,363	01/06/98	Imakawa et al.	435	69.51	
	5,714,377	02/02/98	Tanner et al.	435	254.11	
	5,766,883	6/16/98	Ballance et al.	435	69.7	
	5,844,095	12/1/98	Linsley et al.	530	387.3	
	5,876,969	03/02/99	Fleer et al.	435	69.7	
	5,889,144	03/30/99	Alila et al.	530	300	
	5,948,428	09/07/99	Lee et al.	424	426	
	5,968,510	10/19/99	Linsley et al.	424	141.1	
	5,977,318	11/2/99	Linsley et al.	530	388.0	
	5,981,474	11/9/99	Manning et al.	514	2	
	6,114,146	09/05/00	Herlitschka et al.	435	69.7	
	6,149,911	11/21/00	Binz et al.	424	192.1	
	6,165,470	12/26/00	Becquart et al.	424	185.1	
	6,514,500	2/4/03	Bridon et al.	424	193.1	
	6,686,179	2/3/04	Fleer et al.	435	69.7	
	2004-0010134 A1		Rosen et al.			4/12/01

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Atty. Docket No.	06832.0013	Serial No.	09/832,929
Applicant	Craig A. Rosen et al.		
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	2003-0104578 A1 (and pending claims)		Ballance			10/26/01
	10/702,536 (and pending claims)		Fleer et al.			11/7/03
	10/702,636 (and pending claims)		Fleer et al.			11/7/03
	2003-0054554 A1		Becquart et al.			3/20/03 (publication date)
	2003-0082747 A1		Fleer et al.			5/1/03 (publication date)
	2003-0022308 A1		Fleer et al.			1/30/03 (publication date)
	2003-0036170 A1		Fleer et al.			2/20/03 (publication date)
	2003-0036171 A1		Fleer et al.			2/20/03 (publication date)
	2003-0036172 A1		Fleer et al.			2/20/03 (publication date)
	09/832,501		Ballance et al.			4/12/01
	09/833,041		Rosen et al.			4/12/01
	09/833,111		Rosen et al.			4/12/01
	09/833,117		Rosen et al.			4/12/01
	09/833,118		Rosen et al.			4/12/01

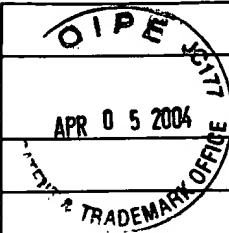
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	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	0 073 646 A2	03/09/83	EPO			
	0 079 739 A2	05/25/83	EPO			
	0 088 632 A2	09/14/83	EPO			
	0 091 527 A2	10/19/83	EPO			
	0 116 201 A1	08/22/84	EPO			
	0 123 294 A1	10/31/84	EPO			
	0 123 544 A2	10/31/84	EPO			
	0 138 437 A2	04/24/85	EPO			
	0 147 198 A3	07/03/85	EPO			
	0 163 406 A1	12/04/85	EPO			
	0 196 056 B1	10/01/86	EPO			
	0 201 239 A1	11/12/86	EPO			
	0 206 733 A1	12/30/86	EPO			
	0 241 435 A2	10/14/87	EPO			
	0 236 210 A1	09/09/87	EPO			English Equivalent
	0 244 221 A1	11/04/87	EPO			
	0 300 466 B1	9/13/95	EPO			
	0 301 670 A1	02/01/89	EPO			
	0 308 381 A1	03/22/89	EPO			
	0 314 317 A1	05/03/89	EPO			
	0 319 641 A1	06/14/89	EPO			

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	0 322 094 A1	06/28/89	EPO			
	0 325 262 A2	07/26/89	EPO			
	0 330 451 A2	08/30/89	EPO			
	0 344 459 A2	12/06/89	EPO			
	0 361 991 A2	04/04/90	EPO			
	0 364 980 B1	04/14/93	EPO			
	0 366 400 A2	05/02/90	EPO			
	0 395 918 A2	11/07/90	EPO			
	0 399 666 B1	11/28/90	EPO			
	0 401 384 B1	3/13/96	EPO			
	0 413 622 B1	02/20/91	EPO			
	0 416 673 A1	03/13/91	EPO			
	0 503 583 A1	09/16/92	EPO			
	0 509 841 A2	10/21/92	EPO			
	0 510 678 A2	10/28/92	EPO			
	0 510 693 A2	10/28/92	EPO			
	0 511 912 A1	11/4/92	EPO			English Equivalent
	0 711 835 A1	05/15/96	EPO			English Equivalent
	0 771 871 A2	07/5/97	EPO			
	1 117790	05/10/89	Japan			Abstract
	1235981A	11/24/99	China			Abstract

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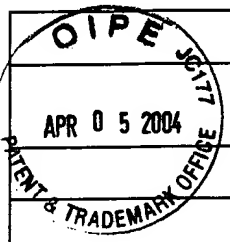
FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	1239103A	12/22/99	China			Abstract
	2 117384	05/01/90	Japan			Abstract
	2 193 631 A	02/17/88	UK			
	2 227079	09/10/90	Japan			Yes
	2 350 362 A	11/29/00	UK			
	2 635 115	09/06/90	France			English Equivalent
	2 719 593	11/10/95	France			English Equivalent
	2022539	02/04/91	Canada			
	3 201987	09/03/91	Japan			Yes
	3 27320	02/5/91	Japan			Abstract
	37 23 781 A1	01/21/88	Germany			English Equivalent
	4 211375	08/03/92	Japan			Abstract
	5 292972	11/09/93	Japan			Abstract
	6 38771	02/15/94	Japan			Abstract
	6-22784	02/01/94	Japan			Abstract
	704594	05/31/95	Australia			
	8 53500	02/27/96	Japan			Abstract
	8 59509	03/05/96	Japan			Abstract
	8-51982	02/27/96	Japan			Abstract
	WO 00/04171	01/27/00	PCT			
	WO 00/23459	04/27/00	PCT			

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WO 00/44772	08/3/00	PCT			
WO 87/03887	07/02/87	PCT			
WO 89/02922	04/06/89	PCT			
WO 90/04788	05/03/90	PCT			
WO 90/13653	11/15/90	PCT			
WO 91/02754	03/07/91	PCT			
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WO 93/00109	01/07/93	PCT			
WO 93/00437	01/07/93	PCT			Yes
WO 93/03164	02/18/93	PCT			
WO 93/15199	08/5/93	PCT			English Equivalent
WO 93/15200	08/05/93	PCT			Yes
WO 93/15211	08/05/93	PCT			English Equivalent
WO 94/25489	11/10/94	PCT			
WO 95/23857	09/08/95	PCT			
WO 95/27059	10/12/95	PCT			
WO 95/30759	11/16/95	PCT			Yes
WO 96/03144 A1	02/08/96	PCT			
WO 96/08512	03/21/96	PCT			
WO 96/14409	05/17/96	PCT			English Equivalent
WO 96/14416	05/17/96	PCT			English Equivalent

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Applicant Craig A. Rosen et al.	
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Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No	
WO 96/18412	06/20/96	PCT				
WO 97/24445	07/10/97	PCT				
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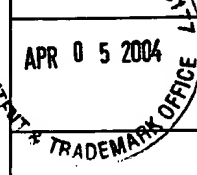
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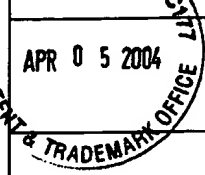
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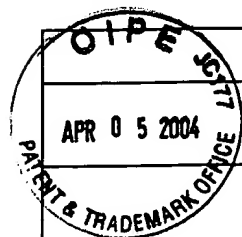
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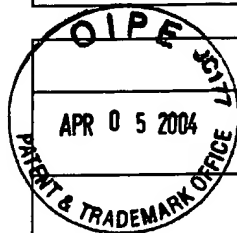
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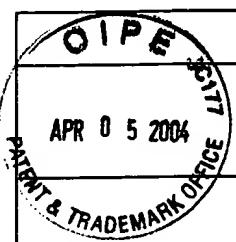
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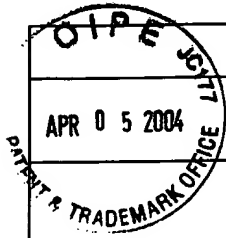
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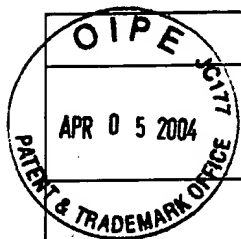
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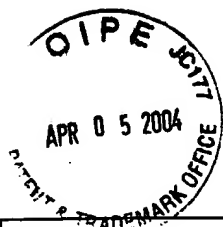
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